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- (58) Field of Search

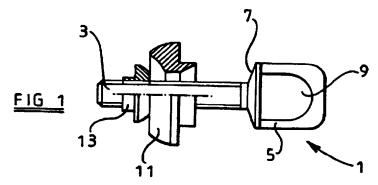
  UK CL (Edition P) A5R RAM RAT

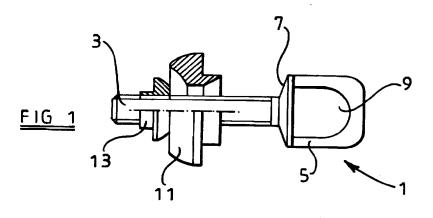
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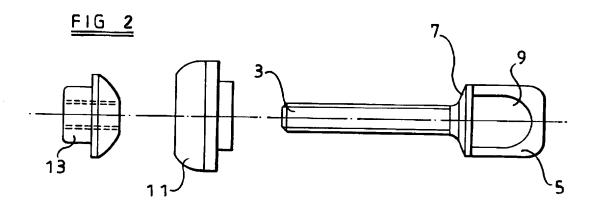
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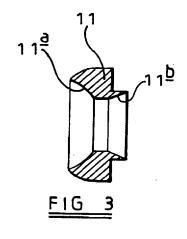
- (54) Abstract Title

  Ligament graft tensioning device
- (57) A surgical device for tensioning ligament grafts comprises retaining means (5) for receiving and holding one end of a ligament, and handle means (3) for enabling the ligament to be held under tension. The tension is maintained by a locking means (11,13) which comprises a crimpable washer (11) and a lock nut (13).

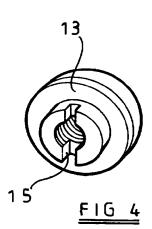


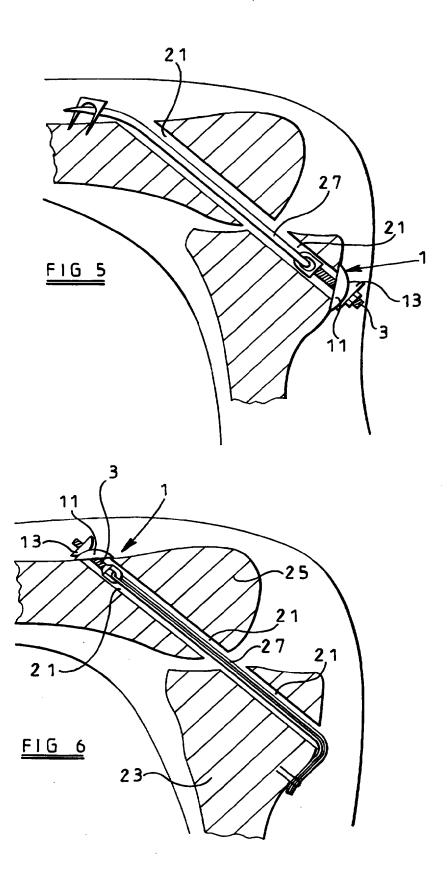






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## A Surgical Device

The invention relates to a surgical device, particularly but not exclusively to a surgical device for tensioning ligaments, for example, when the appropriate ligament has been passed through a channel or a bore in a bone.

Injuries or repair to a knee joint can involve damage to one or more cruciate ligaments which provide anterior-posterior stability to the knee joint. When such damage occurs, a common method of repair involves utilising an auxiliary ligament (prosthetic or soft tissue graft) which can be taken from the Achilles tendon, hamstring or other suitable area. The auxiliary ligament can be placed along side the damaged ligament whilst natural healing takes place or can replace the ligament which is being removed. In either case, a tunnel is formed in the proximal tibia and the distal femur. The auxiliary ligament is then passed through the tunnel from the tibial end slipped through an anchoring washer or other fastener and passed back along the channel or a bore before being suitably tensioned and anchored. Examples of such anchoring devices are disclosed by GB 2288739 and GB 2312376.

A major problem with this type of damage repair is to achieve correct tensioning of the ligament for the ligament to be fully functional in allowing the knee full range of motion. In particular, it needs to be tight enough to give stability without restricting motion. With some ligaments, maintenance of tension during insertion is technically difficult. A surgical device which enables the tension to be adjusted for the whole range of motion to provide optimum tensioning is disclosed by WO92/02196. This device comprises a screw tensioning element for holding one end of the ligament graft. The screw tensioning element is located in the mouth of the tunnel and has means for corporating with a tool which is inserted into the end of the screw tensioning element so that the ligament can be tensioned by appropriate turns of

the screw tensioning element. The screw tensioning element is designed to abut against the side of the bone.

However, such a device is very complicated and difficult to use. In order to tension the ligament, a tool is necessary to turn the screw tensioning element and an accurate "feel" of the tension required can not be achieved by the surgeon. Therefore, adjustment of the tension in the ligament is carried out on a trial and error basis until an optimum is reached. This increases the surgical time required which is distressing to the patient.

The present invention seeks to overcome the above mentioned disadvantages by providing a surgical device for tensioning a ligament in a bone tunnel which allows the surgeon to initially tension the ligament by hand without the need for a complicated device or additional tools to accurately adjust the tension and minimise surgical time.

The invention provides a surgical device as claimed in claim 1. Further advantageous features are set out in subsidiary claims.

The simplicity of the device of the present invention enables the surgeon to grasp the tensioning device to firstly tension the ligament by hand and then finally adjust the tensioning and hold it in place by use of a crimpable washer and nut. This minimises the surgical time and distress caused to the patient.

An embodiment of the present invention will now be described with reference to the accompanying drawings, wherein:

Figure 1 is a side view of the assembled surgical device according to the present invention;

Figure 2 shows the components of the surgical device of the present invention;

Figure 3 shows a cross section of the washer of the surgical device of Figure 2;

Figure 4 shows an alternative to the locking nut of the surgical device of the present invention;

Figure 5 is a schematic diagram illustrating use of the surgical device of Figure 1; and

Figure 6 is a schematic diagram illustrating alternative fixation to that of Figure 5.

The surgical device of the present invention is shown in Figures 1 and 2. The device comprises a screw 1 having a handle means 3 in the form of a shank portion and retaining means 5. The handle means 3 comprises a substantially rigid elongate member which is screw-threaded along its length. The retaining means 5 comprises a flange 7 which is substantially flat and is arranged perpendicular to the longitudinal axis of the handle means 3 at one end thereof and an eye portion 9 which extends from the flange 7.

The device further comprises a crimpable washer 11 and lock nut 13. The bore diameter of the washer 11 is substantially greater than the diameter of the handle means 3 (shank portion) so that there is some play between the washer 11 and shank portion 3, and the outer diameter of the washer 11 is substantially greater than the width of the retaining means 5. With reference to Figure 3, the bore of the washer extends outwardly at each end to form enlarged portion 11a, 11b. The locking nut 13 may have a groove 15 shown in Figure 4, in its outer surface to provide engagement with tool so that the tension in the ligament can be finely adjusted by aid of a tool if necessary. The tool may be set to provide a predetermined tension in the ligament by applying a predetermined torque to the locking 13.

The surgical device described above is made from titanium, cobalt-chrome alloy, stainless steel or another implant-grade material.

Its use will now be described with reference to Figure 5. Figure 5 is a schematic side view of a new joint following an operation to replace a cruciate ligament using the surgical device described above.

A bone tunnel 21 is drilled using standard drilling apparatus and techniques through the proximal tibia 3 and into the distal femur 25. The bone tunnel 21 extends to the outer-surface of the tibia 23 and the femur 25. An auxiliary ligament 27, formed by a prosthetic or soft tissue graft, is looped at least twice through the eye portion 9 of the retaining means 5 of the surgical device. The free ends of the auxiliary ligament 27 are securely anchored to the exterior surface of the fermur 25, or alternatively tibia 28 as shown in Figure 4, by, for example stapling or other suitable fixation means. The surgical device is then introduced into the bone tunnel so that the shank portion; ie the handle means 3, of the screw 1 protrudes out of the bone tunnel 21

and can be held by the surgeon to initially tension the ligament 27 by hand. Thereupon, the crimpable washer 11 and lock nut 13 are placed over the end of the handle means 3 of the screw 1, which protrudes from the bone tunnel 21, and are screwed onto the handle means 3 to a location which provides suitable tensioning of the ligament 27.

The outer diameter of the washer 11 is such that it is greater than the diameter of the bone tunnel 21 and since there is some play between the washer 11 and the shank portion 3, the washer pivots with respect to the shank portion 3 and nut 13 to rest against the outer surface of the tibia 28. The nut therefore lies within the enlarged portion 11a on one side of the washer 11. The washer 11 therefore levels itself against the surface of the bone of provide a secure anchorage for the ligament at the other end of the tunnel 21.

Figure 6 shows an alternative fixtation of the ligament in which the ligament extends through the bone tunnel 21 from the tibia 28 to be secured by the device against the femur 25.

In the light of the disclosure, modifications are described embodiments as well as other embodiments, all within the scope of the appended claims will now become apparent to a person skilled in the art.

## **CLAIMS**

- 1. A surgical device for tensioning ligament grafts, the device comprising retaining means for receiving and holding one end of a ligament graft, and handle means for enabling the ligament graft to be held under tension by hand.
- 2. A surgical device according to claim 1, wherein the device further comprises locking means for maintaining the tension in the ligament graft.
- 3. A surgical device according to claim 2, wherein the locking means provides anchorage for the ligament graft.
- 4. A surgical device according to claim 2 or 3, wherein the locking means comprises a crimpable washer and locking nut.
- 5. A surgical device according to claim 4, wherein the washer is pivotable with respect to the handle means and locking nut.
- 6. A surgical device according to claim 4 or 5, wherein the handle means comprises a screw-threaded, elongate member which engages the locking nut.
- 7. A surgical device according to any one of the preceding claims, wherein the retaining means comprises an eye portion from threading a ligament graft therethrough.
- 8. A surgical device substantially as hereinbefore described with reference to any one of the accompanying drawings.





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GB 9810737.8

Claims searched: 1-8

Examiner:

Peter Davey

Date of search:

19 August 1998

## Patents Act 1977 Search Report under Section 17

### Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.P): A5R (RAM, RAT)

Int Cl (Ed.6): A61F 2/08

Other:

Online: WPI

#### Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
A	WO 92/02196 A1	(JOHNSON), see eg. claim 1 and Fig. 1	1 at least

X Document indicating lack of novelty or inventive step
 Y Document indicating lack of inventive step if combine

Y Document indicating tack of inventive step if combined with one or more other documents of same category.

Member of the same patent family

A Document indicating technological background and/or state of the art.

P Document published on or after the declared priority date but before the filing date of this invention.

E Patent document published on or after, but with priority date earlier than, the filing date of this application.